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SEYFARTH SHAW LLP
55 E. MONROE STREET
SUITE 4200
CHICAGO, IL 60603-5803

EXAMINER	
KRAMER, NICOLE R	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,973	HOFFER, JOAQUIN ANDRES	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 04/24/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the reference DE 4404842 has not been considered.

Claim Objections

2. Claims 43 and 71 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The dependent claims require that the selection of the electrical stimulation signals is based on feedback from the patient. This limitation is already present in the respective parent claim, and thus the dependent claim fails to further limit the parent claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 20-21, 27-28, 30, 38, 42-43, 47, 56, 60-61, and 63 are rejected under 35 U.S.C. 102(a) as being anticipated by "Strategies for providing upper extremity amputees with tactile and hand position feedback" (Riso).

In the previous Office Action dated 7/21/2005, Examiner provided applicant a copy of Riso from Technology and Health Care (Fall 1999). Examiner also provided applicant with citation that the same paper was previously published in "Proceedings of the International Biomechatronics Workshop" on April 1999, and therefore constitutes prior art under 35 U.S.C. 102(a).

Riso discloses a powered arm prosthesis with an integral system that provides cognitive sensory feedback of finger position and grasp forces via stimulation of the relevant afferent nerves within the residual limb (see Abstract and Fig. 4). The system comprises a plurality of sensors in the prosthetic limb, a microprocessor/controller for signal encoding in the prosthetic limb, a multichannel stimulator for receiving information from the microprocessor/controller and producing electrical stimulation signals to stimulate one or more sensory nerve fibers of a severed limb nerve, and a neuro-interface for transmitting electrical stimulation signals to selected sensor nerve fibers (see description of Fig. 4 on pages 406-407). Riso discloses that stimulation of one or more selected sensory nerve fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors (see page 403; section entitled "Microstimulation of tactile afferents"). In addition, Examiner considers the electrical signals to approximate a pattern of sensations that would be

received from a normal, innervated limb before it was amputated because the microelectrical stimulation of small bundles of afferents described in Riso approximates natural sensations more than macrostimulation, which results in a low quality of perceived sensation that remains a foreign feeling resembling a vibration, taping, or flutter on the skin (see page 402 of Riso describing undesirability of macrostimulation). Riso discloses that the microelectrical stimulation should facilitate the independent activation of tactile and muscle afferents (see page 407).

With respect to claims 21, 42-43, 61, and 70-71, Riso discloses that single pulses vs. pulse trains elicit differing patient sensations (see page 403; section entitled "Microstimulation of tactile afferents"). Examiner considers such patient feedback regarding the type of electrical stimulation to anticipate the recitation that the selection of the electrical stimulation signals is based on feedback from the patient.

With respect to claims 27 and 63, Riso discloses finger position and grasp force sensors (see Fig. 4).

With respect to claims 28 and 47, Riso discloses that the means for communicating the sensor signals to the stump are telemetric (communicator in prosthesis/implanted receiver in stump).

With respect to claim 30, Riso discloses an implanted receiver in the stump. The recitation that the electrical stimulation signals are supplied "to alleviate phantom limb pain when the prosthetic limb in not in use" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to claims 38 and 56, Riso discloses several embodiments of microelectrode nerve interfaces (see page 405), including a nerve cuff (embodiments a/b) that circumferentially surround a portion of the nerve. Examiner considers a "multi-chambered nerve cuff" to encompass embodiment (a) of Riso in that embodiment (a) includes a guidance chamber that circumferentially surround a portion of the nerve and a plurality of holes (chambers) each of which represent an addressable electrode contact.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 23-26, 29, 31-37, 41, 44-46, 48-55, 59, and 64-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Strategies for providing upper extremity amputees with tactile and hand position feedback" (Riso).

As described above, Riso discloses a powered arm prosthesis with an integral system that provides cognitive sensory feedback of finger position and grasp forces via stimulation of the relevant afferent nerves within the residual limb (see Abstract and Fig. 4).

With respect to claims 23-26, 29, 44-46, and 48, Riso discloses an embodiment in which the microprocessor is located inside the prosthetic limb and the multi-channel stimulator is implanted in the patient's stump (see Fig. 4). It would have been obvious to one having ordinary skill at the time of applicant's invention to rearrange the parts such that both the microstimulator and the multi-channel stimulator are both within the prosthetic or implanted within the stump, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70.

With respect to claim 31, 41, 49, and 59, Riso discloses that the means for communicating the sensor signals to the stump are telemetric (communicator in prosthesis/implanted receiver in stump). Non-electrical (i.e., telemetric), electrical, and optical signal transmission are all well known in the art and recognized as equivalents. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to use either form of signal transmission because the selection of any of the art-recognized equivalents to transmit signals would be within the level of ordinary skill in the art.

With respect to claims 32-37, 50-55, and 64-69, varying stimulation parameters in order to determine the most optimal configuration is well known in the art. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to vary the stimulation parameters such as amplitude, frequency, and duration, since it has been held that discovering an optimal value of a result effective variable (i.e., the optimal parameters of the electrical signal) involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

7. Claims 22, 62, and 70-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Strategies for providing upper extremity amputees with tactile and hand position feedback" (Riso) in view of U.S. Patent No. 4,232,679 ("Schulman").

As described above, Riso discloses a powered arm prosthesis with an integral system that provides cognitive sensory feedback of finger position and grasp forces via stimulation of the relevant afferent nerves within the residual limb (see Abstract and Fig. 4). Riso fails to disclose that electrical stimulation signals should be provided in the absence of sensory signals in order to alleviate phantom limb pain. Schulman teaches that it is known in the art to stimulate an amputee's severed nerve to alleviate phantom limb pain (col. 1, lines 32-40). It would have been obvious to one having ordinary skill in the art to modify the nerve interface of Riso to stimulate an amputee's severed nerve to alleviate phantom limb pain as taught by Schulman because phantom limb pain may occur when the prosthetic limb is not in use (i.e., when the sensors are not controlling the nerve stimulation).

With respect to claims 72-77, varying stimulation parameters in order to determine the most optimal configuration is well known in the art. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to varying the stimulation parameters such as amplitude, frequency, and duration, since it has been held that discovering an optimal value of a result effective variable (such as the optimal amplitude, frequency, or duration of the electrical signal) involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

8. Claims 39-40 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Strategies for providing upper extremity amputees with tactile and hand position feedback" (Riso) in view of U.S. Patent No. 5,824,027 ("Chen").

Riso discloses several embodiments of microelectrode nerve interfaces (see page 405), including a nerve cuff (embodiments a/b) that circumferentially surround a portion of the nerve. Riso fails to disclose that electrodes are incorporated within a multi-chambered tubular nerve cuff that includes a number of parallel ridges that provide insulation between electrodes. Chen discloses a multi-chambered tubular nerve cuff that may be used to stimulate a severed nerve. The nerve cuff is multi-chambered (30) with a plurality of sealing ridges (28), and the electrodes (34) are segregated into separate chambers of the nerve cuff. It would have been obvious to one having ordinary skill in the art to modify the nerve interface of Riso to incorporate the electrodes in a multi-chambered tubular nerve cuff as taught by Chen because the nerve cuff of Chen provides a customized fit to the shape and size of a nerve at the time of implantation.

With respect to claims 40 and 58, Chen discloses that tubes 42 may be used to deliver pharmacological agents or other chemicals into a chamber (30) through openings (44) (see col. 8, lines 44-55).

9. Claims 60-61 and 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,314,495 ("Kovacs").

Kovacs discloses a microelectronic interface (200/250) comprising a plurality of electrodes (i.e., pairs of microelectrodes 22,24) placed in close proximity to a severed sensory nerve (352) in the limb stump (350) of an amputee. The microelectrode interface is used to localize stimulation or detection of action potential to a particular location on the nerve (see col. 6, line 12-14). When the microelectrode interface acts as a stimulator, it is supplied with electrical current from source 32 to provide electrical stimulation to the nerve. Kovacs discloses that a microprocessor (control processor) generates control signals to a stimulus latch 284 to control each pair of microelectrodes for stimulation purposes (see Fig. 9 and associated text). In addition, Kovacs discloses that prosthetic limb 302 may contains sensors for tactile, position, and force sensing which are transmitted by transceiver 306 to transceiver 304 and through the microelectrode interface to nerve 352 to provide sensory feedback (see col. 15, lines 4-10). Although not explicitly stated, such sensory feedback is necessarily accomplished by utilizing the stimulation mode of the microelectrode interface (in the alternative, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to utilize the stimulation mode of the implanted microelectrode interface to stimulate the sensory nerve in order to provide the person with tactile, position, and force sensation and enhance the function of the prosthetic limb). Examiner considers the electrical signals to approximate a pattern of sensations that would be received from a normal, innervated limb before it was amputated because such signals are applied to

the nerve so that the person can realize tactile, position, and force sensations as would be received from a normal limb before it was amputated.

Kovacs fails to disclose that the selection of one or more sensory nerves fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors. As previously stated, Kovacs discloses that prosthetic limb 302 may contain sensors for tactile, position, and force sensing which are transmitted by transceiver 306 to transceiver 304 and through the microelectrode interface to nerve 352 so that the person can realize tactile, position, and force sensations (see col. 15, lines 4-10). It would have been obvious to one having ordinary skill in the part at the time of applicant's invention to modify the system disclosed in Kovacs such that selection of one or more sensory nerves fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors (i.e., patient feedback that stimulation of particular electrodes results in the desired tactile, position, and/or force sensations) in order to provide the person with accurate tactile, position, and force sensations and enhance the functionality of the prosthetic limb.

With respect to claims 61 and 68-69, Kovacs also fails to disclose that the selection of the electrical stimulation signals is based on feedback from the patient. It is well known to utilize patient feedback for setting effective electrical stimulation parameters such as amplitude and frequency. It would have been obvious to one having ordinary skill in the part at the time of applicant's invention to modify the system disclosed in Kovacs such that selection of the electrical stimulation signals is based on

feedback from the patient (i.e., patient feedback that particular stimulation amplitudes or frequencies result in the desired tactile, position, and/or force sensations) as is well known in the art in order to provide the person with accurate tactile, position, and force sensations and enhance the functionality of the prosthetic limb.

With respect to claims 63-67, varying stimulation parameters in order to determine the most optimal configuration is well known in the art. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to varying the stimulation parameters such as amplitude, frequency, and duration, since it has been held that discovering an optimal value of a result effective variable (such as the optimal amplitude, frequency, or duration of the electrical signal) involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. Claims 62 and 70-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,314,495 ("Kovacs") in view of U.S. Patent No. 4,232,679 ("Schulman").

As described above, Kovacs discloses a microelectronic interface (200/250) comprising a plurality of electrodes (i.e., pairs of microelectrodes 22,24) placed in close proximity to a severed sensory nerve (352) in the limb stump (350) of an amputee. Kovacs fails to disclose that electrical stimulation signals are produced in the absence of sensory signals in order to alleviate phantom limb pain. Schulman teaches that it is known in the art to stimulate an amputee's severed nerve to alleviate phantom limb pain (col. 1, lines 32-40). It would have been obvious to one having ordinary skill in the art to

modify the microelectronic interface of Kovacs to stimulate an amputee's severed nerve to alleviate phantom limb pain as taught by Schulman because phantom limb pain may occur when the prosthetic limb is not in use (i.e., when the sensors are not controlling the nerve stimulation).

Kovacs also fails to disclose that the selection of the electrical stimulation signals is based on feedback from the patient. It is well known to utilize patient feedback for setting effective electrical stimulation parameters such as amplitude and frequency. It would have been obvious to one having ordinary skill in the part at the time of applicant's invention to modify the system disclosed in Kovacs such that selection of the electrical stimulation signals is based on feedback from the patient (i.e., patient feedback that particular stimulation amplitudes or frequencies result in the desired tactile, position, and/or force sensations) as is well known in the art in order to provide the person with accurate tactile, position, and force sensations and enhance the functionality of the prosthetic limb.

With respect to claims 72-77, varying stimulation parameters in order to determine the most optimal configuration is well known in the art. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to varying the stimulation parameters such as amplitude, frequency, and duration, since it has been held that discovering an optimal value of a result effective variable (such as the optimal amplitude, frequency, or duration of the electrical signal) involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

11. Applicant's arguments filed 01/23/06 have been fully considered but they are not persuasive.

12. More particularly, Applicant argues that claims 20-77 are not anticipated by Riso because Riso does not teach generating electrical stimulation signal approximating a pattern of sensations that would be received from a normal, innervated limb before it was amputated (see page 23 of Response filed 1/23/06). However, the quotation from Riso that "the quality of the perceived sensation, moreover, remains a foreign feeling resembling a vibration, taping, or flutter on the skin" relates to the disadvantages of macrostimulation (see page 402 of Riso describing undesirability of macrostimulation). To the contrary, Riso teaches that the microelectrical stimulation should facilitate the independent activation of tactile and muscle afferents (see page 407). Examiner considers the electrical signals to approximate a pattern of sensations that would be received from a normal, innervated limb before it was amputated because the microelectrical stimulation of small bundles of afferents described in Riso approximates natural sensations more than macrostimulation.

Applicant also argues that Riso does not teach the selection of one or more sensory nerves fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors, or the selection of the electrical stimulation signals is based on feedback from the patient. As described above, Examiner considers Riso to disclose that stimulation of one or more selected

sensory nerve fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors (see page 403; section entitled "Microstimulation of tactile afferents"). In addition, Examiner considers Riso to disclose that the selection of the electrical stimulation signals is based on feedback from the patient because Riso discloses that single pulses vs. pulse trains elicit differing patient sensations (see page 403; section entitled "Microstimulation of tactile afferents").

Lastly, Applicant appears to argue that Riso fails to disclose a signal generator for producing electrical stimulation signals to stimulate one or more sensory nerves when there are no sensors involved (see page 24 of Response filed 1/23/06). Examiner agrees that Riso fails to disclose that electrical stimulation signals should be provided in the absence of sensory signals in order to alleviate phantom limb pain. As presented in the above 103 rejection, Schulman teaches that it is known in the art to stimulate an amputee's severed nerve to alleviate phantom limb pain (col. 1, lines 32-40). It would have been obvious to one having ordinary skill in the art to modify the nerve interface of Riso to stimulate an amputee's severed nerve to alleviate phantom limb pain as taught by Schulman because phantom limb pain may occur when the prosthetic limb is not in use (i.e., when the sensors are not controlling the nerve stimulation).

13. Applicant also argues that claims 60-77 are not anticipated by Kovacs because Kovacs does not teach generating electrical stimulation signal approximating a pattern of sensations (see page 17 of Response filed 1/23/06). As described above, Examiner considers the electrical signals to approximate a pattern of sensations that would be

received from a normal, innervated limb before it was amputated because such signals are applied to the nerve so that the person can realize tactile, position, and force sensations as would be received from a normal limb before it was amputated.

Applicant also argues that Kovacs does not teach the selection of one or more sensory nerves fibers is based on feedback from the patient regarding which sensory nerve fibers correspond to which of the plurality of sensors, or the selection of the electrical stimulation signals is based on feedback from the patient. Examiner agrees that Kovacs fails to teach these claim elements, but believes that such claim elements would have been obvious to one having ordinary skill in the art as provided above in the 103 rejection because utilizing patient feedback in setting electrical stimulation configurations and/or parameters is well known in the art.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
2/16/06

George Manuel
Primary Examiner